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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | |
|-----------------|--|----------------------|-------------------------|------------------|--|
| 10/633,735 | 08/04/2003 | Lawrence S. Cousens | 27866/39569 | 5588 | |
| 4743 | 4743 7590 08/01/2005 | | | EXAMINER | |
| | ., GERSTEIN & BOR ER DRIVE, SUITE 630 | PATTERSON, C | PATTERSON, CHARLES L JR | | |
| SEARS TOWN | , | ART UNIT | PAPER NUMBER | | |
| CHICAGO, II | 60606 | | 1652 | | |

DATE MAILED: 08/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | Application No. | Applicant(s) | | | |
|---|--|---------------------------|----------------|--|--|--|
| Office Action Summary | | 10/633,735 | COUSENS ET AL. | | | |
| | | Examiner | Art Unit | | | |
| | | Charles L. Patterson, Jr. | 1652 | | | |
| Period f | The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | |
| Status | | | | | | |
| 1)□ | Responsive to communication(s) filed on | | | | | |
| 2a)□ | This action is FINAL . 2b) ☐ This action is non-final. | | | | | |
| 3)□ | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | | |
| | closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. | | | | | |
| Disposition of Claims | | | | | | |
| 4)⊠ Claim(s) <u>1-42</u> is/are pending in the application. | | | | | | |
| 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | |
| 6)[| 6) Claim(s) is/are rejected. | | | | | |
| 7) | Claim(s) is/are objected to. | • | | | | |
| 8)⊠ | Claim(s) <u>1042</u> are subject to restriction and/or | election requirement. | | | | |
| Application Papers | | | | | | |
| 9) | The specification is objected to by the Examine | r. | | | | |
| - | The drawing(s) filed on is/are: a) acce | | Examiner. | | | |
| | Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | | |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | |
| Priority | under 35 U.S.C. § 119 | • | • | | | |
| 12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). | | | | | | |
| a) All b) Some * c) None of: | | | | | | |
| 1. Certified copies of the priority documents have been received. | | | | | | |
| 2. Certified copies of the priority documents have been received in Application No | | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage | | | | | | |
| application from the International Bureau (PCT Rule 17.2(a)). | | | | | | |
| * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
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| A | 4.) | | | | | |
| Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) | | | | | | |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date | | | | | | |
| 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 5) Notice of Informal Patent Application (PTO-152) 6) Other: | | | | | | |
| | | -, | | | | |

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Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 29-30 and 42, drawn to a PAF-AH enzyme, a pharmaceutical composition comprising the enzyme and a fragment or variant, classified in class 435, subclass 195 and class 424, subclass 94.6.
- II. Claim 2-7, drawn to a method of treating a mammal susceptible to a PAF-mediating condition comprising administering PAF-AH, classified in class 424, subclass 94.6.
- III. Claims 8-11, 13-18 and 23-28, drawn to a polynucleotide of SEQ ID NO: 7 or encoding SEQ ID NO:8, a vector containing the polynucleotide, a host cell and a method of producing PAF-AH using the host cell, classified in class 435, subclass 195, 252.3 and 320.1 and class 536, subclass 23.2.
- IV. Claims 8-10, 12, 15-17 and 24-28, drawn to a polynucleotide of SEQ ID NO:30, a vector containing the polynucleotide, a host cell and a method of producing PAF-AH using the host cell, classified in class 435, subclass 195, 252.3 and 320.1 and class 536, subclass 23.2.
- V. Claims 8-10, 15-17, 19 and 24-28, drawn to a polynucleotide of SEQ ID NO:21, a vector containing the polynucleotide, a host cell and a method of producing PAF-AH using the host cell, classified in class 435, subclass 195, 252.3 and 320.1 and class 536, subclass 23.2.
- VI. Claims 8-10, 15-17, 20, and 24-28, drawn to a polynucleotide of SEQ ID NO:22, a vector containing the polynucleotide, a host cell and a method of producing PAF-AH using the host cell, classified

in class 435, subclass 195, 252.3 and 320.1 and class 536, subclass 23.2.

- VII. Claims 8-10, 15-17; 21 and 24-28, drawn to a polynucleotide of SEQ ID NO:23, a vector containing the polynucleotide, a host cell and a method of producing PAF-AH using the host cell, classified in class 435, subclass 195, 252.3 and 320.1 and class 536, subclass 23.2.
- VIII. Claims 8-10, 15-17, 22 and 24-28, drawn to a polynucleotide of SQ ID NO:24, a vector containing the polynucleotide, a host cell and a method of producing PAF-AH using the host cell, classified in class 435, subclass 195, 252.3 and 320.1 and class 536, subclass 23.2.
- IX. Claims 31-32, 35-36 and 39-40, drawn to a monoclonal antibody 90G11D(ATCC HB 11724), a hybridoma, a hybridoma cell line, a humanized antibody and a method of detecting PAF-AH using the antibody, classified in class 530, subclass 388.1 and class 435, subclass 7.4 and 346.
- XI. Claims 31, 33, 35, 37 and 39-40, drawn to a monoclonal antibody 90F2D(ATCC HB 11725), a hybridoma, a hybridoma cell line, a humanized antibody and a method of detecting PAF-AH using the antibody, classified in class 530, subclass 388.1 and class 435, subclass 7.4 and 346.
- XII. Claims 31, 34 and 38-40, drawn to a monoclonal antibody 143A(ATCC HB 11900), a hybridoma, a hybridoma cell line, a humanized antibody and a method of detecting PAF-AH using the antibody, classified in class 530, subclass 388.1 and class 435, subclass 7.4 and 346.

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XIII. Claim 41, drawn to a method for detecting a genetic lesion in a PAF-AH gene, classified in class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

The products of Groups II, (III-VIII) and (IX-XII) are completely different chemical compounds and are patentably distinct.

Groups III-VIII are drawn to completely different polynucleotides that are structurally different and patentably distinct. Groups IX-XII are drawn to completely different monoclonal antibodies that are structurally different and patentably distinct.

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as for its enzymatic activity not involving treating a particular condition.

Inventions (III-VIII) and XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as producing the PAF-AH enzyme.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different clas-

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sification and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles L. Patterson, Jr., PhD, whose telephone number is 571-272-0936. The examiner can normally be reached on Monday - Friday from 7:30 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Charles L. Patterson, Jr. Primary Examiner

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Patterson July 28, 2005